

Remarks

Claims 22, 31-32, 36, 53 and 55 have been amended. Claims 1-21, 23-24, 33-34, 37-39, and 41-51 have been cancelled without disclaimer of or prejudice to the underlying subject matter. This application presently contains claims 22, 25-32, 35-36, 40, and 52-56. No new matter is added by these amendments. Support for these amendments may be found in the original claims, the sequence listing, the figures, and throughout the specification, *e.g.*, at page 17, line 10 through page 18, line 12; page 48, line 12 through page 53, line 6; page 103, line 18 through page 105, line 20; Examples 1 and 2; and Tables 1 and 4. Applicants respectfully request entry of the foregoing amendments and submit that these amendments put the application in condition for immediate allowance or appeal.

A. Claim Objections

Applicants thank the Examiner for indicating that the objection to claims 24, 34, and 39 has been withdrawn.

B. Rejections under 35 U.S.C. § 112, first paragraph (Written Description)

Claims 22-23, 25-33, 35-38, 40 and 56 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action at page 2. Applicants disagree.

An adequate written description of a genus of nucleic acids may be achieved by means of a “recitation of a representative number of [members], ...or of a recitation of structural features common to the members of the genus.” *Regents of the University of California v. Eli*

Lilly and Co., 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997).

Moreover, the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...*i.e.*, complete or partial structure, other physical and or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (quoting from Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001)).

Applicants respectfully submit that the instant specification complies with the written description requirement. Applicants thank the Examiner for acknowledging that Applicants “have express possession of” the eighteen single nucleotide polymorphisms listed in Table 1. *See, e.g.*, Office Action at page 3. Applicants also note that the instant specification provides the complete nucleotide sequence of SEQ ID NO: 1. Applicants respectfully submit that in combination with the complete nucleotide sequence of SEQ ID NO: 1, the single nucleotide polymorphisms listed in Table 1 reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully disagree with the Office’s rejections on the basis of alleged lack of written description. However, in order to facilitate prosecution, and without acquiescing to the Examiner’s rejection, Applicants have amended claims 22, 32, and 36 and cancelled claims 23, 33 and 37-38 without prejudice to or disclaimer of the underlying subject matter.¹ For at least the foregoing reasons, Applicants submit that the rejection of claims 22-23, 25-33, 35-38, 40 and 56 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description has been overcome or rendered moot. Applicants therefore respectfully request that the written description rejection be withdrawn.

¹ Applicants also note that claims 25-31 and 56 depend from claim 22; claim 35 depends from claim 32; and claim 40 depends from claim 36.

C. *Rejections under 35 U.S.C. § 112, first paragraph (Enablement)*

Claims 22-23, 25-33, 35-38, 40, and 56 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Office Action at page 4. The Office alleges that “the specification does not reasonably provide enablement for using any marker nucleic acid molecule having a nucleic acid sequence that specifically hybridizes to a sequence selected from the group consisting of SEQ ID NO: 1 and complement thereof, and a complementary nucleic acid molecule obtained from a sample.” Office Action at page 4. Applicants respectfully disagree.

Applicants respectfully submit that the specification provides ample guidance to teach the worker of ordinary skill how to make and use the claimed invention without undue experimentation. For example, the specification describes various types of markers (*see, e.g.*, specification at page 103, line 19 through page 106, line 12) and various methods for using a marker nucleic acid molecule to identify a polymorphism and to diagnose glaucoma (*see, e.g.*, specification at page 106, line 12 through page 111, line 8; Example 1; and Table 4). In addition, the specification describes general features of nucleic acid probe hybridization and the selection of PCR primers (*see, e.g.*, specification at page 48, line 12 through page 53, line 6); and provides reference to a number of texts describing basic molecular biology techniques (*see, e.g.*, specification at page 14, line 19 through page 15, line 9). Applicants note that performing routine and well-known steps cannot create undue experimentation even if it is laborious. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

For at least the foregoing reasons, Applicants disagree with the Office’s rejections on the basis of alleged lack of enablement. However, in order to facilitate prosecution, and without acquiescing to the Examiner’s rejection, Applicants have amended claims 22, 32, and

36 and cancelled claims 23, 33 and 37-38 without prejudice to or disclaimer of the underlying subject matter.²

Applicants thank the Examiner for indicating that the claims are “enabling for the marker which is capable of detecting a SNP at location 709 as set forth in Table 4.” Office Action at page 7. Applicants respectfully submit that the specification is also enabling for at least a marker nucleic acid molecule having a sequence capable of specifically detecting a single nucleotide polymorphism at location 391 as set forth in Table 4. *Compare, e.g.,* allelic frequency for SNP 391 in normal-tension glaucoma (“NTG”) patients (62.5%) and in control patients lacking glaucoma (33%) as set forth in Table 4. Applicants further note that “glaucoma” is defined in the specification to include “high tension glaucoma, low tension glaucoma, normal tension glaucoma, and their related diseases.” *See, e.g.,* specification at page 11, lines 5-6. For at least these reasons, Applicants respectfully submit that the claimed invention is fully enabled by the specification.

Accordingly, based on the foregoing, the enablement rejection under 35 U.S.C. § 112, first paragraph, is incorrect and should be withdrawn. Applicants therefore respectfully request that the enablement rejection be withdrawn.

D. Rejections under 35 U.S.C. § 112, first paragraph (Enablement)

Claims 52-55 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Office Action at page 7. Applicants disagree.

² *See infra* note 1.

Applicants respectfully submit that the arguments presented in section C above are sufficient to overcome the Office's rejection of claims 52-55 for alleged lack of enablement. Accordingly, based on the foregoing, the enablement rejection under 35 U.S.C. § 112, first paragraph, is incorrect and should be withdrawn. Applicants therefore respectfully request that the enablement rejection be withdrawn.

E. Rejections under 35 U.S.C. § 112, second paragraph (Claim indefiniteness)

Applicants note that in the Final Office Action, the Office has not addressed the status of the rejections of claims 22-40 under 35 U.S.C. § 112, second paragraph, for alleged claim indefiniteness. Applicants respectfully request clarification of the status of these rejections. For convenience, Applicants reiterate herein their prior arguments regarding the alleged indefiniteness rejections.

Claims 22-40 stand rejected under 35 U.S.C. § 112, second paragraph for claim indefiniteness on the grounds claims 1, 32, and 40 recite "a complementary nucleic acid molecule obtained from a sample." The Office alleges that it is unclear whether or not the complementary nucleic acid molecule from a sample is complementary to the marker nucleic acid molecule. Applicants disagree.

The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied*, 112 S.Ct. 169 (1991). M.P.E.P. § 2173.02 states that "[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

Applicants respectfully submit that claims 22-40 are not indefinite in the recitation of "a complementary nucleic acid obtained from a sample." For example, clause (B) of claim 22

recites "permitting hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule." Applicants submit that a person of ordinary skill in the art reading claim 22 in its entirety and in light of their knowledge of the art would understand (for example, on the basis of clause (B)) that the marker nucleic acid is complementary to said complementary nucleic acid obtained from a sample. Applicants also point out that independent claims 32 and 36 also recite a clause (B) having the same language as clause (B) of claim 22.

Applicants therefore submit that the grounds for the indefiniteness rejections of Claim 22-40 have been obviated or rendered moot. In light of these remarks, Applicants respectfully request withdrawal of these rejections.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is encouraged to contact the undersigned at 202.942.5512 should any additional information be necessary for allowance.

Respectfully submitted,



Joel M. Freed (Reg. Atty. No. 25,101)
David R. Marsh (Reg. Atty. No. 41,408)
Rachel L. Adams (Reg. Atty. No. 54,660)
Lisa A. Adelson (Reg. Atty. No. 51,204)

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ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5000 telephone
(202) 942-5999 facsimile